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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,602	11/21/2003	Samantha K. Holme	(020001)-07-LAV	3118
7590 06/26/2008 ALLEN R. KIPNES, ESQ. WATOV & KIPNES, P.C. P. O. BOX 247 PRINCETON JUNCTION, NJ 08550				
EXAMINER ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
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06/26/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,602

Applicant(s)

HOLME ET AL.

Examiner

LEZAH W. ROBERTS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-30, 33, 35, 36, 39, 40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16, 18, 19, 26-28 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 20-25, 29, 30, 33, 35, 39, 40 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Office Action is in Response the Amendment filed March 14, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 - Anticipation (Previous Rejections)

1) Claims 1-14, 25, 33, 35 and 39-43 were rejected under 35 U.S.C. 102(b) as being anticipated by Day et al. (WO 01/39606). The rejection is maintained in regards to claims 1-8, 33, 39, 40, 42 and 43. The rejection is withdrawn in regards to claims 9-14, 25 and 35. Claim 41 is cancelled.

Applicant's Arguments

Applicant asserts the hydrophobic nature of gum base and how it tends to entrap or materially bind the stain removing components of the instant claims. In accordance with the present invention, these stain removing components are incorporated into a chewing gum composition in a manner where they are not materially bound to the gum base and therefore available to perform an effective stain removing function. Day distributes polyphosphate materials evenly throughout the gum base. Accordingly, the reference teaches that the polyphosphate material is purposely incorporated into the

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gum base in order to achieve uniform distribution therein. One following the teaching of Day with respect to the polyphosphate would be led in a direction directly opposite to that of the present invention which requires keeping the polyphosphate away from the gum base so that it is not materially bound thereto. Day uses softeners for their well known purpose of modifying the texture of gum base and therefore directly incorporates the softeners into the gum base so that it can perform this function. This methodology is directly contrary to the present invention. It is noted that whitening agents are listed among a wide variety of other additives including surfactants. Thus, it follows that there is no teaching or suggestion in this portion of the reference that peroxides are not added directly to the gum base as discussed above in connection with surfactants such as sodium and potassium stearate. To the contrary, listing peroxides with surfactants is a strong indication that peroxides, like surfactants, are added directly to the gum base. Day does not recognize or suggest the importance of keeping stain removing components away from the gum base to the extent that material binding is avoided.

In addition, the present application supports a surprising and unobvious result obtained when the combination of stain removing components are utilized as compared to the individual components alone. The sodium stearate test solution showed an approximate 65% reduction in stain. The solution of sodium tripolyphosphate showed an approximate 95% reduction in stain. The solution of carbamide peroxide showed an approximate 28% reduction in stain. Two of the three test solutions were combined in the same concentration. A surprising and unobvious increase in stain reduction resulted. More specifically, the test solution containing carbamide peroxide and sodium

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stearate would have been expected on a cumulative basis, to exhibit an approximate 93% reduction in stain. Instead, the amount of stain reduction was unexpectedly, 150%. The degree of stain reduction for the test solution containing carbamide peroxide and sodium tripolyphosphate would be expected on a cumulative basis to be approximately 123%. Quite unexpectedly, the test solution exhibited a 180% reduction in stain.

Examiner's Response

Although Day discloses the polyphosphates are distributed throughout the gum base, it also discloses the polyphosphate may be incorporated into the coating of the gums (page 11, lines 35-40). In regards to the whitening agents and surfactants, it is obvious from the reference that these ingredients are active agents and are disclosed to be used in combination with the polymeric active material, especially whitening agents because their purpose is to whiten the teeth. If the components were considered agents as a part of the gum base, they would more than likely be described as such as in the case of waxes where it is stated that these are enclosed in the gum base. Therefore the actives such as peroxides may be included in the coating of the gum in combination with the polyphosphates.

In regards to the unexpected results as disclosed in the remarks on pages 16 and 17, it cannot be determined if the effects disclosed by the results would also be seen when a chewing gum comprises the components. The experiments discussed in the remarks appear to use solutions in the experiments and not chewing gums. Furthermore, the results are not commensurate in scope with the instant claims. The

experiments use carbamide peroxide, sodium stearate and sodium tripolyphosphates at certain amounts. The claims encompass all peroxides, other anionic surfactant and polyphosphates at a wide range of concentrations.

2) Claims 1, 9, 20-22, 24, 33, 39 and 42-43 were rejected under 35 U.S.C. 102(b) as being anticipated by Howard (US 5,824,291). The rejection is maintained.

Applicant's Arguments

Applicant asserts, it is noted that claim 41 is not rejected as anticipated by the reference. As previously indicated, the subject matter of claim 41 has been incorporated into claim 1 and therefore the rejection based on anticipation must be withdrawn for this reason alone. Howard discloses a chewing gum containing a teeth whitening agent. The teeth whitening agent is a peroxyhydrate. As noted beginning at column 4, line 8, plasticizers or softening agents are incorporated within the gum base. As explained above, the incorporation of surfactants within the gum base makes them unavailable for a stain removing function. As indicated in Example I, a softening agent such as vegetable glycerin is added directly to the gum base as indicated at column 6, lines 18-19. It is therefore submitted that Howard does not disclose a chewing gum composition in which multiple stain removing components are available because they are not materially bound to the gum base. Quite clearly, sodium stearate and potassium stearate as examples of common plasticizers (softeners) are purposely incorporated into the gum base to optimize the chewability and mouth feel of the gum (column 2,

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lines 13-14). Furthermore, there is no teaching or suggestion in Howard of the surprising and unobvious stain removing properties obtained by the combination of the stain removing components of the present invention as discussed above in connection with the Day reference.

Examiner's Response

In regards to claim 41, the claim was inadvertently left out of the rejection statement. It is clear from the rejection itself that the reference encompasses claim 41 because the rejection recites "encompassing claims 41-43". The reference discloses that components such as softeners, surface active agents and emulsifiers may be apart of the gum base itself and the water soluble portion of the chewing gum composition. Also when looking to the instant disclosure for guidance as to how to inhibit the active agent from binding to the gum base, the disclosure recites mixing the components directly into the gum base. The reference also teaches these methods and therefore it may be concluded that the ingredients such as softeners and the whitening agents are not materially bound to the gum base because the methods of making the compositions of the reference and that of the instant specification are substantially the same. Based on the instant disclosure it cannot be determined why the active agents are not materially bound because the reference discloses mixing the agents directly with the gum base.

In regards to the unexpected results as disclosed in the remarks on pages 16 and 17, see Examiner's Response above.

3) Claims 1, 2, 9, 13, 14, 20-22, 24, 33 and 41-43 were rejected under 35 U.S.C. 102(b) as being anticipated by Miskewitz (US 5,693,334). The rejection is maintained. Claim 41 is cancelled.

Applicant's Arguments

Applicant argues the reference's composition contains an anionic surfactant which is described beginning at column 3, line 61 as the type of additive that is found in the chewing gum base (i.e. directly incorporated into the chewing gum base). This is further substantiated at column 5, lines 59-63 which shows that the softener is added to enhance the chewability and mouth feel of the chewing gum (i.e. added directly to the gum base). Accordingly, there is no disclosure of the combination of stain removing components as required in neither the present invention nor the manner in which they are incorporated into the chewing gum composition which makes them available for release into the oral cavity to perform a stain removing function. Quite to the contrary, the anionic surfactant in Miskewitz is used as a softener and therefore is incorporated directly into the gum base to soften the gum and improve its texture. In addition, there is no teaching or suggestion of the surprising and unobvious nature of the combination of the stain removing components and the manner in which they are employed in the chewing gum composition of the present invention (i.e. not materially bound to the gum base). The combination of stain removing components produces a stain removing

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reduction which is not expected from the individual components alone as described previously.

Examiner's Response

The surfactants used in the compositions may be anionic surfactants and are not necessarily used in the gum base. Based on the language of the reference, it is clear that it considers surfactants different from softeners and emulsifiers used in the gum base and the surfactants are used to enhance flavor. Also when looking to the instant disclosure for guidance as to how to inhibit the active agent from binding to the gum base, the disclosure recites mixing the components directly into the gum base. The reference also teaches these methods and therefore it may be concluded that the ingredients such as surfactants and peroxides are not materially bound to the gum base because the methods of making the compositions of the reference and that of the instant specification are substantially the same. Based on the instant disclosure it cannot be determined why the active agents are not materially bound because the reference discloses mixing the agents directly with the gum base.

In regards to the unexpected results as disclosed in the remarks on pages 16 and 17, see Examiner's Response above.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 20-24, 29 and 30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (WO 01/39606) in view of Sagel et al (6,582,708). The rejection is maintained. The rejection is maintained in regards to claims 20-23, 29 and 30. The rejection is withdrawn in regards to claim 24.

Applicant's Arguments

Applicant argues in view of the incorporation of the limitation of claim 41 into claim 1, it is respectfully submitted that the claims rejected under the combination of the above mentioned references are patentable. Accordingly, the combination of Day and Sagel does not render any aspect of the claimed invention obvious to one of ordinary skill in the art. This argument is not persuasive.

Examiner's Response

Claim 41 was originally rejected in view of Day and therefore is still encompassed by the Rejection. See rejection above anticipated by Day. Also see arguments above.

2) Claims 44-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (WO 01/39606) in view of Cherukuri et al (4,980,178). The reference is maintained and further applied to claims 9-14, 24, 25 and 35.

Applicant's Arguments

Applicant asserts that it is important to note that Cherukuri, like the other references, teaches the use of plasticizers or softeners to desirably modifier the texture and consistency of the gum base and clearly teaches that these materials (e.g. sodium stearate and potassium stearate) are added directly to the gum base (see column 6, lines 44-51). There is nothing in the reference which teaches or suggests the importance of employing the combination of stain removing components claimed in the present invention and keeping those components in the composition in a manner which does not materially bind them to the gum base. Thus, the citation of Cherukuri does not cure the deficiencies of Day and the rejection of claims 44-46 is deemed improper and should be withdrawn.

Examiner's Response

Day discloses that the active components may be incorporated into the gum coatings as well as the gum base. Cherukuri is used to disclose that active components may also be delivered my incorporating them into the center liquid of a center-filled gum. Using the components in the liquid of the center-fill gum also keeps them from being materially bound to gum base and adds the benefit of a control release mechanism. The reference also discloses that the plasticizers and softening agents may be used in the gum compositions in addition to being incorporated in the gum base indicating that the components are not materially bound to the gum base (col. 9, lines 17-30). These include sodium stearate and potassium stearate. In regards to the amounts, normally, changes in result effective variables are not patentable where the

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difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05 II.

Claims 1-14, 20-25, 29, 30, 33, 35, 39, 40 and 42-46 are rejected.

Claims 15-16, 18, 19, 26-28 and 36 are withdrawn.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612